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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,230	01/29/2002	Noriyuki Ohnishi	2002-0104A	4499

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WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

CEPERLEY, MARY

ART UNIT PAPER NUMBER

1641

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,230

Applicant(s)

OHNISHI ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/03/2002</u> . | 6) <input type="checkbox"/> Other: ____. |

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1) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

2) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3) Claims 3-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The structure of the "biotin-component-containing polymer compound" produced in claim 3 cannot be determined thus rendering the claim indefinite. The structure of "another polymer component" is unspecified and it is unclear both **i)** how the biotin derivative of formula I "polymerizes" and **ii)** how the "copolymerizing" would be effected.

b) Claims 4-29 are indefinite for the reason that the structures of the claimed products cannot be determined. For example, claim 5 states that the "polymer compound" is comprised of "a polymerizable biotin derivative of formula (I)" and "acrylamide or methacrylamide as a copolymer component". However, since both the reactive functional groups of the reactants and the reaction conditions under which the "polymer compound" is formed are unspecified, the structure of the final product cannot be ascertained. For claim 4, what other components are present in the "polymer compound" are unspecified thus rendering the claim indefinite. Similar inadequately defined reactants and reaction conditions appear in the remaining claims; see for example: "a high molecular weight monomer component" (claim 5); "hydrophilic or hydrophobic monomer" (claim 7); the structure of the "biotinylated antibody" and "avidin immobilized heat shock protein or biotinized heat shock protein" complexes of claims 8 and 12; the structure of the "immobilized enzyme" complex of claim 24.

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c) The designation of "the polymer compound" as having the additional elements recited in claims 8-12 is inconsistent with the fact that "the polymer compound" is specifically defined as being a single compound of the structure of formula (I) of claim 1. See also, claims 13+.

d) Product claims 10 and 21-23 improperly contain method of use limitations which do not further limit the product *per se*.

4) Claims 9 and 10 are objected to as being duplicates of claim 8 since all of these claims are drawn to the same "polymer compound". Similarly, claims 18 and 21 are objected to as being duplicates of claim 15; claims 19 and 22 are objected to as being duplicates of claim 16; claims 20 and 23 are objected to as being duplicates of claim 17.

5) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6) Claims 1 and 2 are rejected under 35 U.S.C. 102(b)/(e) as being anticipated by each of Olstein et al (WO 95/31730), Tarasow et al (JACS [1999] vol. 121, pp. 3614-3617), Nelson et al (Nucleosides & Nucleotides [1986], 5(3), pp. 233-241), Roy et al (J. Cem. Soc., Chem. Commun. [1992], pp. 1611-1613), Sigal et al (JACS [1996] 118(16), pp. 3789-3800), BE 898,664, Bosley et al (EP 178,791), Bobrow (U.S. 5,863,748), or Wohlstadter et al (U.S. 6,207,369).

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Each of the references describes a compound comprised of a biotin-linker moiety attached to a terminal vinyl group which anticipates the compounds of instant claims 1 and 2. See

- a)* Olstein et al: page 19, the reaction product of lines 11-13;
- b)* Tarasow et al: Table 1, structure 9;
- c)* Nelson et al : compound 3 of pages 234 and 238;
- d)* Roy et al : page 1612, formula 5;
- e)* Sigal et al: page 1793, formula 7;
- f)* BE 898,664 : page 3, the structure of line 10;
- g)* Bosley et al: page 7, lines 27-35 ; page 10, Example 1;
- h)* Bobrow : col. 7-8, the last structure ;
- i)* Wohlstadter et al: col. 8, section 6.29.

7) Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Olstein et al (WO 95/31730) which describes the polymerization method of instant claim 3 and the biotin-component-containing polymers including copolymers with acrylate and methacrylate of claims 4-6. See page 6, lines 21-29; page 13, lines 13-18; Example 8. The limitations of instant claims 5 and 6 are considered to be inherently present in the polymer compounds of the reference absent evidence to the contrary.

8) Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Roy et al (JCS, Chem. Comm. 1992) which describes the polymerization method of instant claim 3 and the biotin-component-containing polymers including copolymers with acrylate and methacrylate of claims 4-6. See page 1512, structures 13 and 13a . The limitations of instant claims 5 and 6 are considered to be inherently present in the polymer compounds of the reference absent evidence to the contrary.

9) Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigal et al (JACS 1996) which describes the polymerization method of instant claim 3 and the biotin-component-containing

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polymers of claims 4-6 including polyacrylamides. See page 3792, Measurement of the Affinity of the Polymer Inhibitors for the Surface of Influenza Virus: Binding Studies Using Biotin-labeled Polymers. The limitations of instant claims 5 and 6 are considered to be inherently present in the polymer compounds of the reference absent evidence to the contrary.

10) Claims 3-6, 8-10, 15, 16, 18, 19, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosley et al (EP 178,791) which describes the polymerization method of instant claim 3 and the biotin-component-containing polymers of claims 4-6 including copolymers with acrylamide and methacrylamide. See page 11, section 2. The limitations of instant claims 5 and 6 are considered to be inherently present in the polymer compounds of the reference absent evidence to the contrary. For the attachment of avidin/antibody (instant claims 8-10, 15, 16, 18, 19, 21 and 22) see page 13, lines 6-19 and claim 7 of Bosley et al.

11) Claims 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Wohlstadter et al (U.S. 6,207,369) which describes the polymerization method of instant claim 3 and the biotin-component-containing polymers of claims 4-6 including copolymers with acrylamide and methacrylamide. See col. 8, section 6.29. The limitations of instant claims 5 and 6 are considered to be inherently present in the polymer compounds of the reference absent evidence to the contrary.

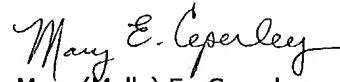
12) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 17, 2004


Mary (Molly) E. Ceperley
Primary Examiner
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